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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,712	09/13/1999	ROBERT W. ESMOND	0609.4440002	4740
75	90 02/12/2003			
ROBERT W. ESMOND			EXAMINER	
302 BLAIR COURT, N.W. VIENNA, VA 22180			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1614	
		DATE MAILED: 02/12/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Examiner Art Unit Visite Kim The MAILING DATE of this communication appears on the cover sheet with the correspondence address - Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE of THIS COMMUNICATION. Is consisted the internal pacified above is as bette hirtory (2014), a egy within he satisfory mixed or firity (30) days with scendened linethy. If the pacific density specified above, the insertions of 3 CRF 1 13(6), in neveral, however, may it may be fitney fred If the pacified renally specified above. The maximum stealary period at apply and will explain \$18(6) MONTHS from the nating date of this communication of thirty (30) days will be considered linethy. If the pacified renally specified above, the maximum stealary period at apply and will explain \$18(6) MONTHS from the nating date of this communication of the pacific or regly is precision size to see the mainting date of this communication, away if linethy fleet, may reduce any server general term adminishment. Sen 37 CRF 1.74(4b). Status I) Responsive to communication (s) filed on 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1, 2,8 and 13-29 is/are pending in the application. 4a) Of the above claim(s) is sidere explained in the application. 4a) The proposed drawing are subjected to a claim for ore consideration. 5 Claim(s) 1, 2,7 and 20-29 is/are rejected. 7 Claim(s) are subjected to a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) The proposed drawing correction filed on is also application is objected to by the Examiner. 10) The drawing(s) filed on is objected to by the Examiner. 11 proposed or orected drawings are required in reply to this Office action. 12 Certified copies of the prior							
Examiner Vickle Kim 1614	· •	Application No.	Applicant(s)				
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The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ② MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Estansions of time may be available under the provisors of 3 C.PR. 1.13(to). In or event, however, may a reply be timely filled. If you bend of many be produced body is the six hand they (D0) days, a largely when the statutory entired and good or reply is specified shore, the marking that produced is not reply to period or reply is specified shore, the marking that produced is not reply to period or reply is specified shore, the marking short produced and good or the statutory period will appear and legisters (M) (MN) His from the rating date of this communication to become ABANCONED (SU.S.C.§ 133). Period of the produced is the statutory period will appear and legisters (M) (MN) His from the rating date of this communication to become ABANCONED (SU.S.C.§ 133). Period of the statutory of the statutory period will appear and legisters (M) (MN) His from the rating date of this communication to become ABANCONED (SU.S.C.§ 133). Period of the statutory of the statutory period will appear and legisters (MN) His section is reply to the resulting date of this communication to become ABANCONED (SU.S.C.§ 133). Period of the statutory of the statutory of the statutory of the scenario of the sc	Office Action Summary	Examiner	Art Unit				
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THE MAILING DATE OF THIS COMMUNICATION. Extensive or time may be available under the procession of 3 CFR 1.15(6). In no event, however, may a raply be timely filed after SIX (8) MONTHS from the mailing date of this communication. It not provide to the process of the communication		ears on the cover sheet with the c	correspondence address				
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	2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal					

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DETAILED ACTION

Request for the Continued examination(RCE) acknowledged

1. The request filed on April 03, 2001 for a RCE under 37 CFR 1.114 based on parent Application No. 09/394,712 is acceptable and a RCE has been established. An action on the RCE follows.

Status of Application

2. The prosecution of this application has been suspended due to the potential interference (request filed on Jan. 02, 2002). However, there are some deficiency was found in the instant claims and the claims are not allowable at this time. Thus, new office action is issued and it supercedes any previous office action.

New Matter

3. The amendment filed 11/22/2000(see paper no.7) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. Claims 1-2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added material which is not supported by the original disclosure is as follows: In claim 1, the proviso

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that said agent is not insulin-like growth factor or a dopamine agonist. Amending claims with the said negative statement can not be used to obviate the previous art rejection because support for the said proviso can not be found in the original disclosure.

Allowable Subject Matter

- 5. Claims 8 and 13-19 are allowed.
- 6. **Reasons for the allowance**: The following is a statement of reasons for the indication of allowable subject matter: US 4,775,665 teaches a method for treating neurological disorders such as Alzheimer's disease using a composition amino acids and insulin releasing carbohydrates. It teaches away from instant invention which is claiming a method comprising restricting carbohydrate diet along with therapeutic modality such as dopamine agonists. Thus, the claimed subject matter is not anticipated nor obvious over the prior art of the record.
- 7. Claims 2 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

9. Claims 1, 20, 21,22, 25 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkerson (US5,326,770).

Wilkerson teaches a 2, 4-thiazolidinedione derivatives(e.g. pioglitazone or a pharmaceutical salt thereof, see column 3, lines 1-10) useful in treating mental disturbances, mental retardation, and memory disorders such as Alzheimer's disease or dementia and m see abstract and column 1 lines 25.

Even though Wilkerson did not mention the biological pathway involving insulin level, the instant claims are not patentably distinct because the limitation recited in the preamble(i.e. increasing insulin sensitivity) is inherent feature which is naturally occurring when the patented composition is used in treating Alzheimer's disease and improving memory. Thus, the claims are anticipated by the cited reference.

10. Claim 1 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Maack et al(WO9513823) or Baker et al(US5,534,615).

Maack et al teach a method of treating Alzheimer's disease using insulin-like growth factor, see claim 1.

Baker et al also teach that insulin-like growth factor that is known as a neurotrophic factor, enhances neuronal survival and growth and thus, it is used in the treatment of Alzheimer's disease, see column 2, lines 39-45.

Thus, the claimed subject matter is not patentably distinct over the cited references.

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As to claim 20, it is noted that the recited limitation (i.e. improving mentation) can be achieved naturally when the insulin-like growth factor is administered to treat Alzhiemer's disease because it is the main characteristic of the Alzheimer's disease and thus, one would have been envisaged the improvement on Alzheimer's disease inherently come along with the improvement on mentation of a patient. Thus, the claim 20 is properly included in this rejection.

11. Claim 1 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wurtman(US 4,775,665) or Dubach et al(WO96/03087).

Wurtman (US'665) teaches a synergistic combination of dopamine agonist comprising choline and tyrosine useful in treating Alzheimer's disease, see abstract, Table I at column 5 and column 1, lines 24-60.

Thus, the claimed subject matter is not patentably distinct over the cited references.

As to claim 20, it is noted that the recited limitation(i.e. improving mentation) can be achieved naturally when any dopamine agonist is administered to treat Alzhiemer's disease because it is the inherent characteristic of the Alzheimer's disease and thus, one would have been envisaged the improvement on mentation of an Alzheimer patent when Alzheimer's disease gets improved. Thus, the claim 20 is properly included in this rejection.

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12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 7, 23-24, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkerson in view of Olesfsky (US 5,478,852).

As mentioned earlier in 102 rejection(supra), Wilkerson teaches a 2,4 thiazolidinedione derivatives effectively used in the treatment of Alzheimer's disease, mental disturbances, mental retardation, and memory disorders such as dementia. Even though Wilkerson broadly teaches the generic formula I of 2,4-thiazolidinedione, he has not specifically included triglitazone or other claimed compound(recited in claims 24-25, 28-29) as a preferred species in his patent.

However, it would have been obvious to one of ordinary skill in the art to substitute pioglitazone with triaglitazone or the compound of instant claim 24-25(its salt) and 28-29 when Wilkerson is taken in view of Olesfsky because Olesfsky teaches pioglitazone and its functionally equivalent species such as triaglitazone in his patent, see column 14, 60-column 15, 30.

One would have been motivated to do so because extension of therapeutic modality is always desirable and beneficial to the users who could advantageous select the drug based on their specific needs and preference. The minor variations including the selection of drug among the functionally equivalent

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species, optimal dosages, or variable formulations in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

- 14. The claims 8 and 13-19 are allowed. The claim 2 is allowable.
- 15. The claims 1, 4 and 20-29 are rejected.

receptionist whose telephone number is 703-308-1235.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the

Vickie Kim, Patent examiner February 5, 2003

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